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| 10/578,615 | 05/08/2006 | Masatoshi Tohata | 288704US0PCT | 3587 |
| 22850 7590 11/21/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | |
| EXAMINER CARLSON, KAREN C | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1656 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/578,615

Applicant(s)

TOHATA ET AL.

Examiner

Karen Cochrane Carlson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15, 17-19, 22-27, 29, 30, 32-34 and 37-51 is/are rejected.
- 7) ☒ Claim(s) 13, 16, 20, 21, 28, 31, 35 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

This Office Action is in response to the paper filed August 20, 2008.

Claims 1-51 are currently pending and are under examination.

Withdrawal of Objections and Rejections:

The objection to the disclosure because of informalities is withdrawn.

The objection to the disclosure because the application does not contain an abstract is withdrawn.

The objection to Claims 4-9 under 37 CFR 1.75(c) as being in improper form is withdrawn.

The rejection of the Claims under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (September 2001; Regulation of the *glv* operon in *Bacillus subtilis*: YfiA (GlvR) is a positive regulator of the operon that is repressed through CcpA and *cre*. Journal of Bacteriology. 183(17): 5110-5121) as set forth in the previous Office Action is withdrawn.

Maintenance of Objections and Rejections:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 2, it is not clear what a functionally equivalent gene is considered to be.

Applicants argue that they can be their own lexicographer and refer to pages throughout the specification which they contend clarifies the scope of the recitation of "functionally equivalent gene" in Claim 2. The Examiner agrees that Applicants can be their own lexicographer. However, as noted above, it is not clear what is intended by this claim language and therefore the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14, 15, 17-19, 22-27, 29, 30, 32-34, 37-42, 44, 45, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (September 2001; Regulation of the *glv* operon in *Bacillus subtilis*: YfiA (GlvR) is a positive regulator of the operon that is repressed through CcpA and *cre*. Journal of Bacteriology. 183(17): 5110-5121).

Yamamoto et al. teach mutant *B. subtilis* 168 comprising plasmids pMV2, pMV2 and pMVR-SD (Table 2).

pMVR comprises nucleotides encoding: bla erm lacZ lacI spac ΔglvR.

pMV2 comprises nucleotides encoding: bla erm lacZ lacI spac ΔglvC.

pMVR-SD comprises nucleotides encoding: bla erm lacZ lacI spac ΔglvR SD sequence.

Therefore, Yamamoto et al. teach a recombinant micro-organism that has at least one gene participating in membrane permeation of maltose has been deleted or knocked out and a gene encoding a heterologous protein LacZ which is a β -galactosidase (EC 3.2.1.23) which is a hydrolase (EC 3) and a cellulase (EC 3.2.1) (**Claim 1, 18, 19, 33, 34**). LacZ is also considered to be a polysaccharide lyase, a synthetase, and transferase because it cleaves lactose to glucose and galactose (**Claims 14, 15, 17, 29, 30, 32, 44, 45, 47, 48, 49**). The deleted gene is glvR or glvC (**Claim 2**), wherein the microorganism is *Bacillus* (**Claim 3**) *subtilis* (**Claim 12, 27, 42**). The plasmids comprise a transcription initiation regulatory gene and a translation initiation regulatory gene (bla, erm), and a secretion signal (β -galactosidase activity was assessed from the cell culture media at page 5116, left col., para. 2, indicating the presence of a secretion signal) is ligated upstream of the LacZ gene (**Claims 4, 5**); the secretion signal is therefore from a cellulase gene from *Bacillus* (**Claim 6, 22**).

The glvC is a PTS maltose specific enzyme IIcB (Abstract, line 2; page 5110, top right col.; **Claim 10, 25, 40**). The glvR is a positive regulator of the glvARC operon (page 5117, right col., last sentence of para. 1; page 5119, left col., para. 2; **Claim 11, 26, 41**).

The regulatory regions for the lacZ gene do not appear to comprise nucleotides 1-659 of either SEQ ID NO: 1 or NO: 3. Therefore, the regulatory regions are a DNA fragment having a nucleotide sequence lacking a portion (all or except possible small fragments comprising contiguous nucleotides) of the nucleotides 1-659 of SEQ ID NO: 1 or NO: 3 (**Claim 7, 37**).

The transformed *B. subtilis* was grown in maltose supplemented media and β -galactosidase activity was assessed (page 5113, right col, para. 1; Fig. 5; **Claims 8, 9, 23, 24, 38, 39**).

New Rejections and Objections:

Claims 7-9, 23, 24 and 37-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 37 refer to DNA fragments having 70% homology to nucleotides 1-659 of SEQ ID NO: 1, for example. Homology is a qualitative variable and not a quantitative variable. Therefore, one cannot know what 70% homology means. Applicants may have intended that the phrase refer to 70% identity.

Claims 8, 9, 23, 24, 38, and 39 are drawn to incomplete methods. For example, in Claim 8 there are no method steps. In Claim 9, there is no purification step.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 5, para. 2 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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Claims 13, 16, 20, 21, 28, 31, 35, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art of Record:

Sawada et al. (US PGPUB 2004/0248279 (US equivalent of WO 2002097064 (Japanese)) teaches to delete or knockout genes involved in sporulation in bacterial cells such as *B. subtilis* 168 and express target proteins including oxidoreductases, transferases, lyases, isomerases ligase/synthetases, and hydrolases such as cellulases, α -amylases, and proteases. The instant SEQ ID NO: 1 and 3 are the same as Sawada sequences SEQ ID NO: 1 and 3 and encode a sporulation associated gene now known as cellulase.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656